

§ 1310.11

(g) An order published by the Administrator in the FEDERAL REGISTER, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) Applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

(2) There is a significant change in the data that led to the issuance of the final rule.

[60 FR 32461, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002]

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–823, 830, and 957–958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the ap-

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plication submitted (indicated as the “date”) are designated as reinstated exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]	

[60 FR 32462, June 22, 1995]

§ 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this section are exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822, 823, 830, 957 and 958) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to this § 1310.12 or § 1310.13 affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts related to exempt chemical mixtures, including distribution in violation of 21 U.S.C. 842(a)(11).

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the “Table of Concentration Limits” are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
N-Acetylanthranilic acid, its salts and esters.	8522	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Anthranilic acid, and its salts and esters.	8530	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	50% by Weight or Volume.	
Benzyl cyanide	8570	20% by Weight or Volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	5% by Weight, net weight includes capsule, if any.	Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.